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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,799	05/04/2005	Graeme Semple	22578-003US1 032.US2.PCT	6923

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EXAMINER	
CHUNG, SUSANNAH LEE	
ART UNIT	**PAPER NUMBER**
1626	

NOTIFICATION DATE	DELIVERY MODE
03/11/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/533,799	SEMPLE ET AL.	
	Examiner	Art Unit	
	SUSANNAH CHUNG	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,20 and 26-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,20 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/19/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14, 20 and 26-29 are pending in the instant application. Claims 15-19 and 21-25 are canceled.

Information Disclosure Statement

The information disclosure statement (IDS), filed on 12/19/2008 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Response to Non-Final Office Action

Acknowledgment is made of applicant's response and amendment of the claims filed on 12/19/2008.

Claims 20-21 and 26-27 were rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. In particular, Claims 20-21 and 26-27 were directed to methods of treating a metabolic-related disorder comprising administering to an individual in need of such treatment a therapeutically effective amount of a pharmaceutical composition of claim 13 or of a compound of claim 1. Applicants amendment to the claims, IDS, and response have been carefully considered. Applicants clarify that hRUP38 is Applicants internal designation of the Human Orphan G-Protein-Coupled Receptor GPR109b, which is stated in the references. In view of this and the references previously cited the disorders dyslipidemia, atherosclerosis and type 2 diabetes are allowable. Coronary heart disease and insulin resistance are overly broad terms that could encompass a number of diseases and are not enabled. Therefore, claims 20 and 26 stand rejected. Claims 27 and 29 are objected to as being based on a rejected claim.

Claims 1, 2 12, 13 and 28 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds and compositions of formula (I), does not reasonably provide enablement for solvates or hydrates of those compounds. The claims have been amended so that all the instantly pending claims read on solvates and hydrates. Applicants arguments and amendments to the claims have been carefully considered, but are not found persuasive. Applicants state that the preparation of solvates and hydrates is "substantially easier." See Response page 17 of 29. Examiner respectfully disagrees. See office action mailed on 6/27/08, page 9. The scope of solvates and hydrates that could be formed is unpredictable. Applicants point to Table 1 of the specification in the making of a monoclonal antibody as one step in making a solvate or hydrate. Applicants state to add water or a solvent, but Applicants do not point to any examples of specific solvates or hydrates or the use of a solvate or hydrate. Absent guidance in the specification regarding solvates and hydrates, the scope of a solvate or hydrate of the instantly claimed compound is unpredictable. Therefore, claims 1-14, 20 and 26-29 stand rejected for the claims limitation directed to solvates and hydrates.

Claim 14 was rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. The agents in the claim were rejected, but Applicants point to page 39-40 of the specification where the terms are defined. Therefore, this rejection is withdrawn.

Claims 1, 2, 4, 5, 6, 7, 8, 12, 13, and 28 were rejected under 35 U.S.C. 102(b) as being anticipated by Raeymaekers, et al (U.S. Pat. No. 4,943,574). Applicants arguments and amendments to the claims have been carefully considered. The proviso is acknowledged and the claims drawn to the proviso are withdrawn. Claims 13 and 14 drawn to a pharmaceutical composition are maintained. Applicants state that the pharmaceutical composition of 1-butyl-

1H-benzotriazole-5-carboxylic acid is not disclosed and that this compound is an intermediate and outside the scope of the final product. Examiner respectfully disagrees. The structure of 1-butyl-1H-benzotriazole-5-carboxylic acid and the final products claimed in US Pat No 4,943,574 are so similar that when US Pat No 4,943,574 states in column 20, approximately lines 42-44 that the examples are intended to illustrate and not limit the scope of the invention, one of ordinary skill in the art would recognize that the pharmaceutical composition is an inherent characteristic of the 1-butyl-1H-benzotriazole-5-carboxylic acid because of the close structural similarity of 1-butyl-1H-benzotriazole-5-carboxylic acid to the final compounds claimed in the patent. Therefore, the anticipation rejection of claims 13, 14 and 28 are maintained.

Claims 1-14 and 28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Raeymaekers, et al (U.S. Pat. No. 4,943,574). Applicants arguments and response have been carefully considered, but are not found persuasive. Raeymaekers teaches the process of making 1-butyl-1H-benzotriazole-5-carboxylic acid and obvious derivatives thereof. Applicants argue that this is an intermediate and that this compound has different properties from the final product. Examiner respectfully disagrees and asserts that one of ordinary skill in the art when faced with US Pat No 4,943,574, which states in column 20, approximately lines 42-44 that the examples are intended to illustrate and not limit the scope of the invention, one of ordinary skill in the art would recognize that the intermediate compounds, which are close in structural similarity to the final product would have similar properties. Raeymaekers discloses very specific methods of making obvious derivatives of the instantly claimed compounds in columns 20-35, Examples 1-16. This obviousness rejection is based on the close structural similarity between the prior art compounds and instantly claimed compounds. The motivation is that compounds close in

structure will exhibit similar pharmacological properties. Therefore, absent unexpected results, claims 1-14 and 28 are obvious in view of Raeymaekers.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Golam M. M. Shameem/
Primary Examiner, Art Unit 1626

Susannah Chung